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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,725	03/25/2004	Frank A. Chan	7404-602	8166
41577	7590	04/24/2006	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Period for Reply

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2005 and 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. _____
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) ☐ Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date 8/15/05, 3/25/04. 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 6, 20-21 and 29-30 are objected to because of the following informalities:

In regards to claims 6 and 29, remove "further comprising:" at line 1.

In regards to claim 20, at line 1, "the expression element" should apparently read --the expression member-- or --an expression element-- to avoid a potential lack of antecedent basis problem.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 5-7, 10-14, 17-22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Searle et al. (US Patent Application Publication No. 2002/0087180).

In regards to claim 1, Searle et al. disclose(s) a sampling device 10, comprising:
a lancet 14 configured to form an incision in skin;
an expression member 12 having a band 20 for receiving the lancet 14; wherein
the band 20 is moveable between a relaxed position over the incision in skin and a
contracted position over the incision;

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a compression member 16 configured to contact and traverse the expression member 12 wherein the band 20 compresses from the relaxed position to the contracted position to express bodily fluid from the incision in skin;

a housing configured to contact the skin near the incision; and

wherein at least a portion 24 of the expression member 12 is resilient in order to return to the relaxed position (see figs. 2 and 7-8; see par 0026).

It is noted that the expression member 12 of Searle et al. is moveable between a relaxed position and a contracted position; as such, the band expression and all of its components (i.e. band, lancet, fingers) can be construed as moveable between a relaxed position and a contracted position (see claim 1 of Searle et al.).

In regards to claim 2, Searle et al. disclose(s) a sampling device 10 wherein the band 20 has an annular shape (see fig. 2).

In regards to claim 5, Searle et al. disclose(s) a sampling device 10 wherein the band 20 is resilient (see figs. 7-8; see par 0021, at lines 6-8).

In regards to claim 6, Searle et al. disclose(s) a sampling device 10 further comprising:

wherein the expression member 12 includes a skin contacting portion 18 capable of surrounding the band 20 and wherein the skin contacting portion 18 is moveable between a relaxed position over the incision in skin and a contracted position over the incision to express bodily fluid from the incision in skin (see figs. 7-8).

In regards to claim 7, Searle et al. disclose(s) a sampling device 10 wherein the housing has a concave shape (see figs. 7-8).

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In regards to claim 10, Searle et al. disclose(s) a sampling device 10 wherein the compression member 16 includes a passageway 42 to at least partially receive the expression member 12 (see figs. 7-8; see par 0026).

In regards to claim 11, Searle et al. disclose(s) a sampling device 10 wherein the band 20 is capable of contact the skin (see figs. 7-8).

In regards to claim 12, Searle et al. disclose(s) a sampling device 10, comprising:
an expression member 12 having a skin contacting portion 18 that is moveable between a relaxed position over an incision in skin and a contracted position over an incision;

a compression member 16 configured to contact the skin contacting portion 18 of the expression member 12 to move the skin contacting portion 18 from the relaxed position to the contracted position;

a housing to contact the skin near the incision; and

wherein at least a portion of the expression member 12 is resilient in order to return to the relaxed position (see figs. 2 and 7-8; see par 0026).

In regards to claim 13, Searle et al. disclose(s) a sampling device 10, wherein the expression member 12 includes a passageway 20 that is moveable between a relaxed position over the incision in the skin and a contracted position over the incision (see figs. 7-8).

In regards to claim 14, Searle et al. disclose(s) a sampling device 10, wherein the passageway 42 is resilient (see figs. 7-8; see par 0021, at lines 6-8).

In regards to claim 17, Searle et al. disclose(s) a sampling device 10, wherein the expression member 12 includes at least one resilient band 20 (see figs. 7-8).

In regards to claim 18, Searle et al. disclose(s) a sampling device 10, wherein the band 20 is configured to express bodily fluid from the incision (see figs. 2 & 7-8).

In regards to claim 19, Searle et al. disclose(s) a sampling device 10, wherein the band 20 has an annular shape (see fig. 2).

In regards to claim 20, Searle et al. disclose(s) a sampling device 10, wherein the expression element includes at least one resilient finger 24 (see figs. 7-8).

In regards to claim 21, Searle et al. disclose(s) a sampling device 10, wherein the finger 24 is configured to express bodily fluid from the incision (see figs. 7-8).

In regards to claim 22, Searle et al. disclose(s) a sampling device 10, further comprising a lancet 14 configured to form the incision in skin (see figs. 7-8).

In regards to claim 25, Searle et al. disclose(s) a sampling device 10, wherein the housing is a concave shape (see figs. 7-8).

4. Claims 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (US Patent No. 6,332,871).

In regards to claim 26, Douglas et al. disclose(s) a method of expressing a body fluid, comprising:

positioning a sampling device 1 over an incision in skin;

wherein the sampling device 1 includes a housing to contact the skin near the incision; and

expressing body fluid from the incision with the sampling device 1 by repeatedly squeezing and compressing the skin around the incision to allow body fluid to flow to the incision (see figs. 4F-G & 12A-12B; column 6/lines 11-27; column 16/lines 31-34 & 59-67; column 17/lines 3-10).

In regards to claim 27, Searle et al. disclose(s) a method of expressing a body fluid, further comprising:

forming the incision in skin with a lancet 30 of the sampling device 1 (see figs. 12A-12B).

In regards to claim 28, Douglas et al. disclose(s) a method of expressing a body fluid, further comprising: collecting the body fluid with a test strip 83 of the sampling device 1 (see figs. 12A-12B).

In regards to claim 29, Douglas et al. disclose(s) a method of expressing a body fluid, further comprising:

wherein the sampling device 1 includes an expression member 25 to resiliently move from a relaxed position to a contracted position in which the skin near the incision is squeezed and compressed (see figs. 12A-B; column 6/lines 11-27).

In regards to claim 30, Douglas et al. disclose(s) a method of expressing a body fluid, wherein the expression member 25 moves from the contracted position to the relaxed position (see figs. 12A-B; column 6/lines 11-27).

In regards to claim 31, Douglas et al. disclose(s) a method of expressing a body fluid, wherein the housing is a concave shape to urge body fluid towards the incision in skin (see figs. 12A-B).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-4 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Searle et al. ('180) in view of Lange et al. (US Patent No. 5,318,584).

Searle et al. disclose(s) a sampling device 10, as described above, that teaches all the limitations of the claims except Searle et al. do not teach lobes. However, Lange et al. disclose a sampling device comprising lobes 29 (see figs. 1, 5 & 7). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Searle et al. with lobes similar to that of Lange et al. in order to releasably lock the expression and compression members together (i.e. by replacing the system of elements 48 with a lobe system similar to those of Lange et al.) so as to be able to allow the cannula to travel and lock (see column 5/lines 34-44).

7. Claims 8-9 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Searle et al. ('180) in view of Mitchen (US Patent No. 5,014,718).

Searle et al. disclose(s) a sampling device 10, as described above, that teaches all the limitations of the claims except Searle et al. do not teach a test strip. However, Mitchen discloses a sampling device 1 comprising a test strip 19 (see figs. 2-4). It would

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have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Searle et al. with a test strip similar to that of Mitchen in order to test the body fluid (see Mitchen, column 3/lines 12-16).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,752,817 to Flora et al. discloses a split pressure ring for lancing device and method of operation.

US Patent Application No. 2005/0085839 to Allen et al. discloses a lancing device with a floating probe for control of penetration.

US Patent No. 5,540,709 to Ramel discloses a lancet device comprising a body and a base.

US Patent No. 5,964,718 to Duchon et al. discloses a body fluid sampling device comprising an expression ring.

US Patent No. 6,537,242 to Palmer discloses a method and apparatus for enhancing penetration of a member for intradermal sampling or administration of a substance.

US Patent No. 6,056,765 to Bajaj et al. discloses lancet device with an adjustable digit-constricting member.

US Patent No. 2,646,799 to Jacoby, Jr. discloses a blood lancet.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758.

The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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